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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,502	06/16/2006	Kenneth A Murdock	67762.010151	9989

56188 7590 12/01/2008

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EXAMINER	
TATE, CHRISTOPHER ROBIN	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
12/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,502	MURDOCK ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *1-20 and 34-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group II, claims 21-33, and the species "vascular disease" in the reply filed on 01 October 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 21-33 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating or alleviating one or more diseases or injuries induced by pathological free radicals - including the elected species (i.e., vascular disease) , does not reasonably provide enablement for preventing such diseases/injuries (including preventing vascular disease). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art;

With respect to the Wands factors above (particular as they pertain to the quantity of experimentation necessary as well as the state of the prior art within the medical field), Applicants have reasonably demonstrated/disclosed that the claimed Acai-based composition is useful as a therapeutic agent for treating one or more diseases or injuries induced by pathological free radicals - including the elected species (i.e., vascular disease) in a patient in need thereof. However, the claims also encompass using the claimed Acai-based composition to prevent such diseases or injuries which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "treating" or "alleviating" especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than, e.g., certain vaccination regimes) - including preventing any and all diseases and injuries induced by pathological free radicals (which encompasses a plethora of potential clinical manifestations).

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the instantly claimed Acai-based composition in a manner so as to provide the functional effect instantly claimed with respect to "preventing" any and all diseases and injuries induced by pathological free radicals (including preventing vascular disease).

It is strongly suggested that the phrase "preventing or" be omitted from claim 30 to overcome this rejection (in addition, to hasten prosecution, it is also strongly suggested that the method of use claims - i.e., claims 30-33, be limited to treating or alleviating vascular disease via the instantly claimed underlying function effect concerning pathological free radical reactions).

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-23 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bobbio et al. (Acta Alimentaria, 2002).

A freeze-dried composition of *Euterpe oleracea* (also known as Acai) fruit pulp is claimed. Dependent claims include the composition further comprising a pharmaceutically acceptable carrier.

The cited reference discloses a commercial freeze-dried Acai fruit preparation which appears to be identical to the presently claimed freeze-dried Acai fruit pulp composition for the following reasons. The reference commercial freeze-dried Acai preparation is obtained from a water extract of Acai fruit (please note that the reference water extract of Acai fruit would inherently contain naturally-occurring fruit pulp dispersed therein), is a stabilized preparation containing high levels of naturally-occurring anthocyanins therein (including, e.g., above the minimum levels instantly claimed), and is combined with a solvent and/or buffer solution - either of which reasonably read upon pharmaceutically acceptable carriers (as instantly claimed) - see entire document including page 372).

In the alternative, even if the claimed Acai composition is not identical to the referenced Acai composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced Acai composition is likely to inherently possess the same characteristics of the claimed Acai composition particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed Acai composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the USC 102/103 rejection above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' composition differs (including with respect to the various properties/characteristics

thereof - as instantly claimed) and, if so, to what extent, from that disclosed by the cited reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

It is also noted that the cited reference does not teach that the composition can be used in the manner instantly claimed (i.e., as a dietary supplement). However, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Please note that when applicant claims a composition in terms of function and the composition of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection (MPEP 2112).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bobbio et al. (Acta Alimentaria, 2002).

Bobbio et al. teach the preparation of a freeze-dried Acai fruit water extract (which would intrinsically contain fruit pulp dispersed therein) which beneficially provides stability to the pigmented anthocyanin components therein. Bobbio also beneficially discloses that this fruit grows easily in the northern part of Brazil, that from its small black fruits, a thick black extract is prepared with water and widely used in Brazil as an energy and health drink, and that the red pigmented anthocyanins therein is an important source of use in foods (see entire document including pages 371-372).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the commercial freeze-dried Acai fruit preparation taught by Bobbio et al. within an energy and health drink and/or within other food products, since the cited reference beneficially teaches that Acai fruit preparations are used as such, and that freeze-drying provides a means of stabilizing the valuable pigmented anthocyanins therein. Please note that orally consuming an energy/health drink or other food containing such a freeze-dried Acai fruit preparation reasonably reads upon administering the freeze-dried Acai fruit preparation in a manner consistent with "preventing" one or more of the recited pathological free radical reaction afflictions instantly claimed, including the elected species - vascular disease. In addition, since pathological free radical reactions are continually occurring in all mammals/humans (i.e., all mammals including humans are constantly exposed to free radical reactions), consuming an energy/health drink or other food containing such a freeze-dried Acai fruit preparation also reasonably reads upon administering the freeze-dried Acai fruit preparation in a manner consistent with "alleviating" one or more of the recited pathological free radical reaction afflictions instantly claimed. It would also have been obvious to prepare such a freeze-dried

Acai fruit pulp composition via the instantly claimed steps (as recited by claims 24-29) since all the initial steps therein are notoriously well known (although not necessarily in printed publications) to be conventional processing steps used in fruit processing industry - i.e., harvesting and weighing the fruit (necessary/conventional steps done by most fruit farmers/processors), cleaning and washing the fruit with hot water for a short duration (a basic hygienic step done during conventional fruit processing to remove debris, harmful contaminants, etc), and removing the skin/outer peel therefrom (hulling the fruit). From these initial conventionally employed steps, it would have been obvious to prepare a freeze-dried extract of the fruit pulp (as a commercial freeze-dried water extract thereof as taught by Bobbio et al. - intrinsically containing the fruit pulp dispersed therein) via the final two steps recited in claim 24, since these are well known conventional steps used to prepare stabilized freeze-dried preparations thereof. Accordingly, the adjustment of these and other types of conventional working conditions are deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Please note that the various properties instantly claimed would be intrinsic to such a freeze-dried Acai preparation.

Thus, the invention as a whole is *prima facie* obvious, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/
Primary Examiner, Art Unit 1655